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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/821,839	03/29/2001	Hong Ma	PSU-0020	3569

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 04/25/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/821,839

Applicant(s)

MA, HONG

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on February 3, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 12-14, 17-18, 25 and 26 is/are pending in the application.
- 4a) Of the above claim(s) 25 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 12-14, 17 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

The Amendment filed February 3, 2003, paper no.13, has been entered.

Claim 9 is cancelled.

Claims 1, 3, 5, 8 and 14 are newly amended.

Claims 1-8, 12-14, 17-18 and 25-26 are pending.

Claims 25-26 are withdrawn from consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Claim Objections

Claim 5 is objected to because of the following informalities: the word "of" between "acid" and "molecule" should be deleted.

Claim Rejections - 35 USC § 112

Claims 5 and 14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 5 and 14 as amended are directed to a sequence encoding an amino acid sequence "at least 70% identical to a cyclin domain comprising amino acids 361 through 521 of SEQ ID NO:2". The limitation "at least 70% identical to a cyclin

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domain comprising amino acids 361 through 521 of SEQ ID NO:2" does not find support in the specification and thus constitutes new matter.

Claims 1-4 and 12-13 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed October 23, 2002.

Applicant's arguments filed February 3, 2003, have been fully considered but they are not persuasive.

Applicant argues that the specification describes the claimed nucleic acids in terms which are adequate to allow one of skill in the art to distinguish them from other isolated nucleic acids. Applicant also argues that while not describing the precise sequence of the isolated nucleic acid, the molecules are adequately described with respect to their functional properties. Applicant points out that the specification provides a functional description of the gene as a regulator of meiosis and as a meiosis-specific cyclin that activates a cyclin-dependent kinase. Applicant also points out that the specification describes the sequence from a biochemical perspective as a cyclin, and describes the chromosomal location and phenotypic characteristics of the expression of the sequence. Applicant additionally points out that the specification provides a DNA sequence for a representative gene in the sequence listing, and argues that the combination of the sequence information, biochemical function, and phenotypic characterization provided make the structure of the claimed molecule clear to those of skill in the art (reply pages 6-11).

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The Office maintains that the claims are directed to a nucleic acid that is not adequately described with respect to its structural or functional properties. First, although the specification discloses a correlation between the nucleic acid of SEQ ID NO:1 and a mutation which results in the failure to maintain homolog attachment during meiotic prophase I, the disclosed correlation does not describe the specific function of the polypeptide encoded by SEQ ID NO:1. Furthermore, while the specification discloses that the C-terminus of the polypeptide encoded by SEQ ID NO:1 has amino acid sequence homology to the cyclin box motif of cyclin proteins, the disclosed amino acid sequence homology does not demonstrate that the polypeptide encoded by SEQ ID NO:1 has a cyclin function. Also, none of the recited claims recite a specific function for the claimed nucleic acid molecules. Second, the rejected claims do not recite a specific structure for the claimed nucleic acid molecules. Absent the recitation of a particular nucleotide sequence that is correlated with a specific function, the claimed nucleotide sequences are not adequately described.

Claims 1-8, 12-14 and 17-18 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record set forth in the office action mailed October 23, 2002.

Applicant's arguments filed February 3, 2003, have been fully considered but they are not persuasive.

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Applicant argues that the functions of the gene and its encoded polypeptide are described throughout the specification. Applicants also argue that the function of a gene can be determined by its disruption and observation of lost functions. Applicant asserts that the gene in question encodes a meiosis-specific cyclin that activates a cyclin-dependent kinase to regulate the activities of other proteins that maintain homolog attachment. Applicant also argues that eliminating allegedly inoperative embodiments would be routine (reply pages 13-15).

The Office maintains that the functions asserted in the specification for the claimed nucleic acids are speculative. The Office further maintains that while gene disruption and observation of lost function may be useful in the process of assigning a function for the product of a particular gene, confirmation of protein function by some form of testing is required to enable the claimed invention. Applicant provides no empirical evidence that the claimed nucleic acid encodes a cyclin that activates a cyclin-dependent kinase, as the assignment of cyclin function appears to be based solely on amino acid homology between the C-terminus of the protein encoded by SEQ ID NO:1 and known cyclin proteins. Additionally, the Office maintains that eliminating inoperative embodiments would not be routine because the specification provides no guidance with respect to what characteristics of SEQ ID NO:1 would be retained by sequences homologous to SEQ ID NO:1 that encode functional proteins, such that one skilled in the art could determine without undue experimentation which sequences to test for the desired function.

Claim 3 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "approximately".

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Applicant argues that the term "approximately" can be considered a definite term used to avoid a strict numerical boundary to the specified parameter, and that approximately is a term that is commonly used in patents issued by the USPTO, including biotechnology patents.

Applicant also argues that the specification provides sufficient guidance as to the metes and bounds of "approximately" as used in the context of the instant invention (reply pages 4-5).

The Office considers only the use of the term "approximately" as it is used in the context of the instant invention, as each case is examined on its own merits. The Office maintains that "approximately" as used in the context of the instant invention is indefinite because the number and nature of the amino acids that make up a polypeptide can have a direct effect on its function, and the specification does not provide guidance with respect to the means by which such an approximation could be made. Furthermore, because different methods of approximation are used by those skilled in the art, the use of the term "approximately" here without further clarification is indefinite.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is indefinite in the recitation of "abnormal". It is unclear what type of chromosome attachment abnormality is intended, as chromosome attachment can be "abnormal" in a variety of different ways.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the

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invention. Claim 3 is indefinite in the recitation of "one or more exons" in conjunction with "that form an open reading frame having a sequence that encodes a polypeptide approximately 578 amino acids in length". It is unclear whether each exon would encode a polypeptide approximately 578 amino acids in length, or whether the combination of one or more exons would encode a polypeptide approximately 578 amino acids in length.

Claims 8 and 14(a) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 8 and 14(a) are indefinite in the recitation of "sequence of the one or more exons of SEQ ID NO:1" and "sequence comprising the exons of SEQ ID NO:1". It is unclear whether all of the exons add up to one copy of SEQ ID NO:1, or multiple copies of SEQ ID NO:1.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 14 is indefinite in the recitation of "consisting essentially of" because it is unclear what would or would not materially affect the basic and novel characteristic(s) of the claimed invention.

Claim 14(b) is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 14(b) is indefinite in the recitation of "at least 80% identical to the exons of

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SEQ ID NO:1". It is unclear whether the claimed sequence is 80% identical to the entire sequence of SEQ ID NO:1, or whether the claimed sequence is 80% identical to each of the exons of SEQ ID NO:1.

Claim Rejections - 35 USC § 101

Claims 1-8, 12-14 and 17-18 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility, and under 35 U.S.C. 112, first paragraph, because one skilled in the art clearly would not know how to use the claimed invention, for the reasons of record set forth in the office action mailed October 23, 2002.

Applicant's arguments filed February 3, 2003, have been fully considered but they are not persuasive.

Applicant argues that the invention has a well established utility, as the specification teaches that pollen is allergenic to humans and other organisms, such that plants mutant in SDS, having defective pollen and male sterility, could be beneficial to the public. Applicant also points out that the specification teaches that phenotypes associated with SDS can be used for plant breeding. Applicant additionally points out that the specification teaches that the nucleic acids and proteins of the instant invention would have utility in making male sterile or pollen deficient plants. Furthermore, Applicant argues that the specification supports the role of SDS as a cyclin as the specification discloses extensive data comparing mutant and wild type cells and chromosomes throughout the meiotic cycle, as well as meiosis specific expression and data on revertants (reply pages 17-18).

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That plants mutant in SDS could be beneficial to the public does not support the assertion of a well established utility because the structure and function of the claimed nucleic acids is not disclosed in the prior art. Additionally, the disclosure does not provide any empirical evidence that the claimed nucleic acids can be used to make male sterile or pollen deficient plants that would be useful for plant breeding. Furthermore, the data disclosed in the specification do not conclusively support a specific function for the claimed nucleic acids because the data only correlate the expression of the claimed nucleic acids with the general process of meiosis, which requires the activity of numerous structurally and functionally distinct molecules.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Grant et al. (Proc Natl Acad Sci U S A. 1998 Dec 22;95(26):15843-8).

Claim 1 as amended is drawn to an isolated DNA molecule comprising a sequence of a gene located on *Arabidopsis thaliana* chromosome 1, the disruption of said gene resulting in a phenotype of abnormal homologous chromosome attachment during the meiotic prophase I.

Grant et al. teach a gene sequence (page 15844 Figure 1; page 15846 Figure 3). While Grant et al. do not teach that their sequence is “of a gene located on *Arabidopsis thaliana* chromosome 1, the disruption of said gene resulting in a phenotype of abnormal homologous

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chromosome attachment during the meiotic prophase I", the quoted phrase is not interpreted as limiting "a sequence of a gene", as "a sequence of a gene" can read on any DNA sequence of any size from any source.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210.

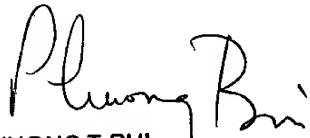
The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
April 21, 2003


PHUONG T. BUI
PRIMARY EXAMINER
4/21/03